K101003

X. THE 510(k) SUMMARY

Submitted by:

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DEC 10 2010

Contact Person:

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Date Prepared:

3 December 2010

Trade Name:

RapidVit™ Blast
RapidWarm™ Blast

Common Name:

Vitrification freeze kit for blastocysts
Vitrification thaw kit for blastocysts

Classification Name:

Reproductive Media and Supplements
(21 C.F.R. § 884.6180)

Predicate Devices:

RapidVit™ Cleave and RapidWarm™ Cleave (K080446) from Vitrolife, and
Vit Kit™ - Freeze and Vit Kit™ - Thaw from Irvine Scientific Co., Inc. (K060168)

Description of the Device:

RapidVit™ Blast and RapidWarm™ Blast is a device used for vitrification and warming of human blastocysts. The cryoprotectants 1,2-propanediol and ethylene glycol are used together with sucrose for dehydration of the embryo before cryopreservation.

RapidVit™ Blast consists of three different solutions with increasing concentrations of cryoprotectants intended to prepare the human blastocysts for vitrification by reducing the intracellular water content and increasing the osmolality. Also RapidWarm™ Blast consists of three different solutions with decreasing concentrations of sucrose to restore the water content and osmolality in embryo during warming after vitrification storage.

Intended Use:	RapidVit™ Blast is intended for vitrification of human blastocyst stage embryos RapidWarm™ Blast is intended for warming of vitrified human blastocyst stage embryos

Technological Characteristics:

RapidVit™ Blast and RapidWarm™ Blast are devices used for vitrification of blastocysts. The cryoprotectants 1,2-propanediol and ethylene glycol are used together with sucrose for dehydration of the embryo before cryopreservation.

For RapidVit™ Blast and RapidWarm™ Blast two predicate devices have been utilized:

RapidVit™ Cleave and RapidWarm™ Cleave as predicate device
The RapidVit™ Blast and RapidWarm™ Blast device is a modification of the RapidVit™ Cleave and RapidWarm™ Cleave device (K080446) currently marketed by Vitrolife Sweden AB for the vitrification of day 3 cleavage stage embryos.

RapidVit™ Blast and RapidWarm™ Blast is similar to the predicate device in most respects. However, the predicate device RapidVit™ Cleave and RapidWarm™ Cleave (K080446) is intended for vitrification of day 3 cleavage stage embryos. RapidVit™ Blast and RapidWarm™ Blast and the predicate device consist of the same components but in somewhat different proportions as they are tailor-made for blastocysts and for cleavage stage embryos respectively.

Vit Kit™ - Freeze/Vit Kit™ - Thaw as predicate device
Vit Kit™ - Freeze/Vit Kit™ - Thaw and RapidVit™ Cleave/RapidWarm™ Cleave are embryo-physiological solutions supplemented with permeable and non-permeable cryoprotectants.

Main differences between Vit Kit™ - Freeze/Vit Kit™ - Thaw and RapidVit™ Blast/RapidWarm™ Blast

The main differences between RapidVit™ Blast and RapidWarm™ Blast and Vit Kit™ - Freeze and Vit Kit™ - Thaw are the following:

- Vit Kit™ - Freeze and Vit Kit™ - Thaw contain ethylene glycol, DMSO and sucrose as cryoprotectants, while RapidVit™ Blast and RapidWarm™ Blast contain ethylene glycol, 1,2-propanediol and sucrose

- Vit Kit™ - Freeze and Vit Kit™ - Thaw use an HEPES buffer, while RapidVit™ Blast and RapidWarm™ Blast use a MOPS buffer to keep the pH within physiological values during handling outside the incubator

Justification for use of different media composition

The justification for this comparison, in spite of the somewhat different media composition for RapidVit™ Blast/RapidWarm™ Blast and Vit Kit™ - Freeze/Vit Kit™ - Thaw, is as follows:

- Most ART centres are now using either 1,2-propanediol or DMSO as the cryoprotectant of choice for cryopreservation of embryos. 1,2-propanediol is considered less toxic for embryos and for users

- The MOPS buffer used in RapidVit™ Blast and RapidWarm™ Blast is similar to HEPES which is used in Vit Kit™ - Freeze and Vit Kit™ - Thaw. In addition the MOPS buffer is used in most of the IVF Media from Vitrolife, and has been used clinically for a very long time with good results

Successful vitrification of animal and human blastocyst stage embryos by use of RapidVit™ Blast and RapidWarm™ Blast has been shown in the nonclinical and clinical studies referred to below.

Nonclinical studies

Three studies have been performed with vitrified surplus human blastocysts using RapidVit™ Blast and RapidWarm™ Blast. All studies showed good survival, development and hatching rate of the blastocysts. One study also included fluorescence in situ hybridisation analysis for chromosomal abnormalities and vitrified embryos showed equal or higher number of normal cells then non vitrified fresh blastocysts.

Clinical studies

The clinical investigation of RapidVit™ Blast and RapidWarm™ Blast confirmed the preclinical findings, showing that the majority of the blastocysts survive vitrification and warming. The investigation also confirmed that vitrification using RapidVit™ Blast and RapidWarm™ Blast can be used with good results in the daily treatment of IVF patients. All patients undergoing transfer of previously vitrified and warmed blastocysts during the study time period have been included in the data analysis. The reported pregnancy rate is between 24% and 43% per embryo transfer. So far 43 health babies with normal outcomes have been born from vitrified and warmed blastocysts after the use of RapidVit™ Blast and RapidWarm™ Blast. No adverse effects or complications have been noticed in the study and the results are similar to results with other FDA approved devices.

Conclusions on Nonclinical and Clinical studies

Based on the findings during the nonclinical and clinical investigations, RapidVit™ Blast and RapidWarm™ Blast has showed to be as safe, efficient and performs as well as similar FDA approved devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Kjell Kjörk
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DEC 10 2010

Re: K101003
Trade Name: RapidVit™ Blast and RapidWarm™ Blast
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: November 23, 2010
Received: November 26, 2010

Dear Mr. Kjörk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101003

XI. INDICATIONS FOR USE STATEMENT

DEC 10 2010

510(k) Number (if known): K101003

Device Name: RapidVit™ Blast
RapidWarm™ Blast

Indications for Use: RapidVit™ Blast is indicated for vitrification of human blastocyst stage embryos

RapidWarm™ Blast is indicated for warming of vitrified human blastocyst stage embryos

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use_____
(Per 21 C.F.R. § 801.109)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101003